



Patent Docket P2026R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>re Application of Liu et al. Serial No.: 10/813,483 Filed: March 29, 2004 For: HIGH CONCENTRATION ANTIBODY AND PROTEIN FORMULATIONS</p>	<p>Group Art Unit: 1644 Examiner: Yunsoo Kim Confirmation No: 5594 CUSTOMER NO: 09157 EXPRESS MAIL EL 872102831 US June 23, 2005</p>
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

37 CFR §1.97(c)

- by the applicants after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the

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application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

The patent which is marked with an asterisk (*) in the attached PTO-1449 form is not supplied because this application was filed after June 30, 2003. Applicants are no longer required to submit copies of U.S. patents and U.S. patent application publications cited in information disclosure statements for all U.S. national patent applications filed after June 30, 2003 and for all international patent applications that have entered the national stage under 35 U.S.C. §371 after June 30, 2003 (1276 OG 55). Nevertheless, applicants stand ready to provide copies at the request of the Examiner.

A concise explanation of relevance of the items listed on PTO-1449 is:

not given

Serial No.: 10/813,483

- given for each listed item
- given for only non-English language listed item(s) [Required]
- in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: June 23, 2005 By: Craig G. Svoboda

Craig G. Svoboda
Reg. No. 39,044
Telephone No. (650) 225-1489



FORM PTO-1449		JUN 22 2005		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P2026R1		Serial No. 10/813,483	
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Liu et al.					
				Filing Date 29 Mar 2004		Group 1644			
U.S. PATENT DOCUMENTS									
Examiner Initials		Document Number	Date	Name		Class	Subclass	Filing Date	
	*25	6,541,606	01.04.03	Margolin et al.					
FOREIGN PATENT DOCUMENTS									
Examiner Initials		Document Number	Date	Country		Class	Subclass	Translation Yes No	
	26	2002/072636	19.09.02	WO					
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)									
	27	Carpenter et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice" <u>Pharmaceutical Research</u> 14(8):969-975 (1997)							
	28	Presented by The University of Colorado Center for Pharmaceutical Biotechnology, "2003 Colorado Protein Stability Conference", Breckenridge, Colorado (July 17-19, 2003)							
Examiner					Date Considered				

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.